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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,052	11/22/2006	Kimihiro Mabuchi	19461-004US1 547267	2047

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EXAMINER
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CHRISTIAN, MARJORIE ELLEN

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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11/12/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,052	<b>Applicant(s)</b> MABUCHI ET AL.	
	<b>Examiner</b> MARJORIE CHRISTIAN	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 8-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/7/2006 &amp; 12/4/2006</u> .                                | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

1. This is the initial Office action based on the application filed June 7<sup>th</sup>, 2006.
2. Claims 1-16 are pending. Claims 1-7 have been fully considered and claims 8-16 are drawn to a non-elected invention.

### ***Election/Restrictions***

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 1-7, drawn to a "hollow fiber bundle wherein the content of hydrophilic polymer on the outer surface is 25-50 mass %".

Group 2, claims 8-16, drawn to processes of drying a hollow fiber.

The inventions listed as Groups 1-2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The subject matter of Group 1 concerns "a hollow fiber bundle wherein the content of hydrophilic polymer on the outer surface is 25-50 mass %". In contrast, the subject matter of Group 2 merely

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describes how the polysulfone-based selectively permeable hollow fiber bundle should be dried. Since the subject matters do not describe that the hollow fiber membrane contains a "hydrophilic polymer", the method in Group 2 is not considered a method for manufacturing the hollow fiber membrane bundle related to Group 1.

During a telephone conversation with Samuel Borodach on 10/24/2008 a provisional election was made without traverse to prosecute the invention of Group 1, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Priority***

4. Receipt is acknowledged of papers (JP 2003-410871) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

5. The information disclosure statement filed December 4<sup>th</sup>, 2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. A concise explanation of the relevance of JP 61-232860 has not been included. It has been placed in the application file, but the information referred to therein has not been considered.

The other items in the information disclosure statement have been considered, items not considered have been lined through.

***Claim Rejections - 35 USC § 103***

6. **Claims 1-2, 4-7 are rejected under 35 USC 103 (a) as being obvious over EP 0 997 182, FUKE et al. (hereinafter FUKE) in view of US Patent No. 5,071,887, NAKAGAWA et al. (hereinafter NAKAGAWA) as further evidenced by US Patent No. 6,605,218 KOZAWA et al. (hereinafter KOZAWA).**

As to Claim 1, FUKE discloses a bundle of selectively permeable polysulfone-based hollow fiber membranes (Abstract) wherein the amount of hydrophilic polymer eluted is inhibited by cross-linking using radiation (Paragraph 19, Page 4), such that the amount of water-soluble PVP becomes 5 to 50% of the total amount ***[amount of hydrophilic polymer eluting from each hollow fiber is not larger than 10ppm]***. FUKE does not explicitly disclose that the elution rate is not larger than 10 ppm however it is implicit that the elution rate can be in that range, this is further evidenced by KOZAWA. KOZAWA discloses that the amount of hydrophilic polymer eluted is not higher than 10ppm (Abstract). FUKE also discloses that the surface PVP concentration ***[hydrophilic polymer]*** is in the range of 30% to 45% (Para. 23). FUKE does not appear to expressly disclose the UV absorbance of the test solution obtained from pieces of fiber. However, NAKAGAWA discloses a test solution obtained from pieces of fiber to a length of 2 cm, where the solution is capable of being from ten fractions of the bundle obtained at regular lengthwise intervals, absent evidence to the contrary; the test

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method for eluted matter is based on Approval Standard for Dialysis-type Artificial Kidney (C6/L26-27); and it is implicit that the difference between the maximum and minimum out of the maximum values of UV absorbance of the extracted solution from the fractions is not larger than 0.05, absent evidence to the contrary, and in view of the fact that is desirable to reduce the amount of elution since the absorbance of the test solution is not more than 0.1 at a wavelength of 220 nm to 350 nm, (C6/L25-52).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the polysulfone-based hollow fiber of FUKU to include the UV absorbance of the fibers in a test solution of NAKAGAWA. The motivation would have been to have a standard test method for eluted matter (C6/L25). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to Claim 2, it is inherent that the hollow fiber bundle of FUKU (in view of NAKAGAWA) has *substantially no partial* sticking of the hollow fiber membranes in the lengthwise direction, absent evidence to the contrary. This is further evidenced by the fact that the partial sticking occurs when the hydrophilic polymer content is high and that FUKU reduces the amount of hydrophilic content by a washing method (Page 6, Para. 30-31, 33-34) similar to that disclosed in the instant specification (where the washing method is for the express purpose of substantially reducing the partial sticking).

As to Claim 4, FUKU (in view of NAKAGAWA) discloses that the proportion of polyvinyl pyrrolidone to polysulfone is 1 to 10% by weight, where polyvinyl pyrrolidone is

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the hydrophilic polymer (Claim 1) ***[mass ratio of hydrophilic polymer to polysulfone-based resin is 1 to 20 mass %]***.

As to Claims 5 and 6, FUKU (in view of NAKAGAWA) discloses that the hydrophilic polymer is poly(vinylpyrrolidone) (Abstract) and it is crosslinked by irradiation so that it is insolubilized (Page 4, Line 55).

As to Claim 7, FUKU (in view of NAKAGAWA) discloses that the hollow fiber membrane is for purifying blood (Page 3, Paragraph 11) ***[bundle is used in a blood purifier]***.

7. **Claim 3** is rejected under 35 USC 103 (a) as being obvious over EP 0 997 182, FUKU et al. (hereinafter FUKU) in view of US Patent No. 5,071,887, NAKAGAWA et al. (hereinafter NAKAGAWA) in further view of US Patent No. 5,514,413, VAN'T HOFT et al. (hereinafter VAN'T HOFT).

As to Claim 3, FUKU (in view of NAKAGAWA) discloses a pore diameter distribution in the outer wall of the membrane (Para. 37-38). FUKU does not appear to explicitly disclose the specific range of the porosity on the outer surface. However, VAN'T HOFT discloses a surface porosity of 1 to 20% (Column 3, Lines 6-7) ***[porosity of the outer surface is 8 to 25%]***.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the porosity of the hollow fiber membrane of FUKU (in view of NAKAGAWA) to include the specific surface porosity of VAN'T HOFT. The suggestion would have been to have sufficient porosity to ensure nominal resistance to gas

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transport and have a polymeric substrate that meets the strength, thermal stability and process compatibility for the membrane (C3/L1-6). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### **Conclusion**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571)272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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MC

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797